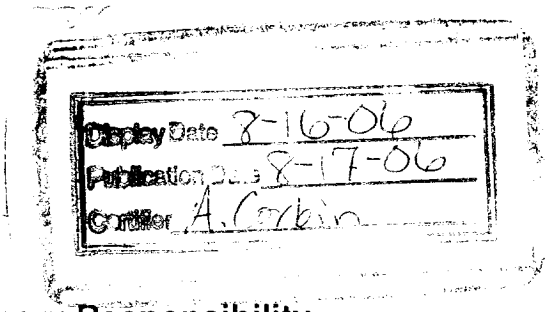

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Heparin Catheter Lock-Flush Solutions; Transfer of Primary Responsibility from Center for Drug Evaluation and Research to Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; announcement of transfer.

SUMMARY: The Food and Drug Administration (FDA) is announcing the transfer of primary responsibility for the regulation of heparin catheter lock-flush solution products from the Center for Drug Evaluation and Research (CDER) to the Center for Devices and Radiological Health (CDRH). These products are combination drug-device products. The transfer of lead review responsibility to CDRH is based on FDA's determination that the primary mode of action for these heparin catheter lock-flush solution products is that of the device part of the combination. The transfer provides consistency and efficiency in the regulation of these combination products by treating like products similarly.

DATES: The effective date of the transfer is [*insert date 60 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: James S. Cohen, Office of the Commissioner (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

For questions on what to submit in the 510(k) submission: Sheila A.

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Murphe, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., rm. 350AA, Rockville, MD 20850, 301–443–8913, ext. 203.

SUPPLEMENTARY INFORMATION: Heparin catheter lock-flush solution products are intended to enhance the performance of intravascular catheters. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings that are inserted into a patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. Heparin catheter lock-flush solutions are periodically inserted into and stored within the catheter to keep the catheter patent and to prevent blood from clotting within the catheter between uses.

Prior to the mid-1990's, heparin catheter lock-flush solution products were regulated under the new drug and abbreviated new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act), with CDER serving as the lead agency review component. Many of the available marketed products were approved under abbreviated new drug applications ("generic drugs"). However, more recently, based on several jurisdictional determinations by FDA for specific products, applications for catheter lock-flush solutions containing anticoagulant, such as heparin, or antimicrobial components have been assigned to CDRH and regulated under the device provisions of the act. FDA is now transferring the applications for heparin catheter lock-flush solution products that are in CDER to reflect these more current jurisdictional determinations.

Heparin catheter lock-flush solutions are intended to maintain patency when the catheter is not being used to sample blood, monitor blood pressure, or administer fluids to the patient. The solution component of the product (i.e.,

sterile saline or sterile water) acts by physically occupying space within the intravenous catheter and exerting pressure on the patient's circulating blood. This action helps to prevent the patient's blood from backfilling into the catheter, clotting, and contributing to microbial contamination. When acting in this way, the solution meets the definition of a device in the act in that it affects the structure or function of the body, and does not achieve its primary intended purposes through chemical or metabolic action (21 U.S.C. 321(h)). Likewise, the heparin (i.e. the anticoagulant) component of the product meets the definition of a drug in that it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and is intended to affect the structure or function of the body of man (21 U.S.C. 321(g)).

Catheter lock-flush solutions that contain both drug and device components are combination products as defined in 21 CFR 3.2(e)(1). FDA is responsible for assigning combination products to a lead agency Center for regulation based upon the agency's determination of the combination product's "primary mode of action." (See 21 U.S.C. 353(g)(1) and 21 CFR 3.4.) FDA has determined that the primary mode of action of heparin catheter lock-flush solution products in maintaining catheter patency is attributable to the device component's role in physically occupying space and applying pressure within the catheter. FDA likewise has determined that the drug component of the product (heparin) performs a secondary role by acting chemically to prevent thrombotic occlusions within the catheter.

Accordingly, to enhance consistency and efficiency in the regulation of these combination products by treating like products similarly, FDA is transferring primary review responsibility from CDER to CDRH for heparin catheter lock-flush solution products that have been regulated under the drug

provisions of the act. The transferred products will be reviewed and regulated under the device provisions of the act. As with all combination products, CDRH will consult with CDER regarding the drug components of these products as appropriate. Catheter lock-flush solutions that contain only water or saline are considered devices rather than combination products and are regulated under the device provisions of the act.

The agency intends to assist manufacturers of currently marketed heparin catheter lock- flush solution products in the transition from approved new drug applications (NDAs) or approved abbreviated new drug applications (ANDAs) to 510(k) submissions under the device provisions of the act. Based upon the submissions made and the prior review of these products under the drug provisions of the act, FDA has determined that heparin catheter lock-flush solution products approved under these particular approved NDAs or ANDAs are substantially equivalent to heparin catheter lock-flush solution products cleared for marketing under section 510(k) of the act (21 U.S.C. 360(k)) and the approved NDAs or ANDAs will be considered cleared device premarket notifications (510(k) clearances) under section 510(k) when FDA has provided the sponsor written notification of the transfer and its effective date. No application user fees will be assessed for this administrative transfer. NDA and ANDA manufacturers that have previously notified FDA (i.e. before the date of this notice) that they have discontinued marketing their heparin catheter lock-flush solution products will be subject to review and clearance of a 510(k) submission prior to marketing their product again.

Heparin catheter lock-flush solution products are accessories to, and regulated along with, intravascular catheters as Class II devices (special controls). (See 21 CFR 880.5200.) Upon the effective date of the transfer, the

transferred products will be subject to the provisions of section 510(k) of the act and its implementing regulations (part 807 (21 CFR part 807)). The transferred products will be subject to the general control provisions of section 513 of the act, including the Registration and Listing regulation (part 807), the Quality System Regulation (part 820 (21 CFR part 820)), and the Medical Device Reporting regulation (21 CFR part 803).

Manufacturers planning to change or modify the design, components, method of manufacture, or intended use of a transferred heparin catheter lock-flush solution product should evaluate whether a 510(k) submission is required for the change or modification as set forth in § 807.81(a)(3). If a 510(k) submission is required, the manufacturer should cite in its initial submission the NDA or ANDA number held for the product and include a copy of the letter sent from FDA notifying the sponsor of the transfer of review responsibility to CDRH.

FDA finds that there is a substantial likelihood that failure to comply with the Quality System Regulation (part 820) for this product will potentially present a serious risk to human health. Therefore, future 510(k) submissions for heparin catheter lock-flush solution products will be subject to pre-clearance inspections in accordance with section 513(f)(5) of the act (21 U.S.C. 360c).

FDA will contact applicants holding approved NDAs or ANDAs that it believes have products affected by this transfer. Holders of applications subject to transfer, holders of applications for discontinued heparin catheter lock-flush solutions products, or holders of applications for catheter lock-flush solution products with other ingredients who are uncertain as to which agency Center

has primary jurisdiction, should contact James S. Cohen (see the **FOR FURTHER INFORMATION CONTACT** section).

Dated: 8/9/06
August 9, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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